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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,923	12/19/2001	James Thacker	8109.003.USDV	9929

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EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/020,923	THACKER, JAMES	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-19, 25-30, 33-36* is/are pending in the application.

4a) Of the above claim(s) *6-10,12-19 and 25-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,29,30 and 33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 17, 2006 has been entered.

Amendment Entry

2. The amendment filed October 17, 2006 has been entered. Claims 6-10, 12-19 and 25-28 have been withdrawn. Claims 1-5, 20-24 and 31-32 have been cancelled. Claims 33-36 have been newly added. Thus, claims 11, 29-30 and 33-36 are under consideration in this office action.

Withdrawal of Objections and Rejections

3. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 11 and 29-32 under 35 U.S.C. 112, second paragraph: and

b) The rejection of claims 11 and 29-32 under 35 U.S.C. 103(a) as being unpatentable over Shih et al., (US Patent 4,026,767 published May 31, 1977) in view of Harlow and Lane (1986);

Response to Arguments

4. Applicant's arguments with respect to claims 11 and 29-30 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 11, 29-30 and 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a method for detecting 10,000 cfu/ml or less of microorganisms comprising a method that is performed in less than eight hours. Applicant did not point to support in the

specification for the method being performed in less than eight hours. Applicants point to pages 6-9 for support, however page 7 states that

> After an incubation period which may be from minutes to hours to days, and is preferably less than about twenty four hours, less than about eight hours, less than about two hours, and more preferably less than about thirty minutes, microorganisms are digested in a manner to produce cell fragments with the viability marker adsorbed to the surfaces of the cellular debris.

Thus, the specification teaches that the incubation is less than eight hours. There is no teaching that the entire method is performed in less than eight hours. Thus, there appears to be no teaching of the instantly recited method. Therefore, it appears that there is no support in the specification. Applicants must specifically point to page and line number support for the identity of a method for detecting 10,000 cfu/ml or less of microorganisms comprising a method that is performed in less than eight hours. Therefore, the amended claims incorporate new matter and are accordingly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 11, 29-30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shih et al.,(US Patent 4,026,767 dated May 31, 1977) in view of Litman et al., (US Patent 4,379,925 dated February 22, 1983).

The claims are drawn to a method for detecting 10,000 cfu/ml or less of microorganisms comprising: incubating the microorganisms with a nutrient medium containing a predetermined amount of a viability substrate, wherein metabolism of said viability substrate by the microorganisms produces a viability marker; digesting the microorganism; incubating the digested microorganisms with a primary antibody specific for the viability marker; conjugating the primary antibody to a reporter molecule to form a reporter-primary antibody complex; detecting reporter molecules that form reporter-primary antibody complex and determining the amount microorganisms from the reporter-primary antibody complexes detected, wherein the microorganisms are bacteria and the method is performed in less than eight hours. The dependant claims are drawn to time periods, reporter molecules, sample types and the microorganisms.

Shih et al., teach a method for indicating the presence of microorganisms in blood or other fluids comprising introducing the material to be tested into a nutrient medium containing a ditetrazolium chloride which converts to detectable blue color component in response to dehydrogenase reduction which takes place when microorganisms are present, incubating the said nutrient medium for a short period of time, and then examining the incubated product whereby a blue coloration is indicative of the presence of microorganisms in the sample (see abstract). Examples 1 and 2 teach the culture nutrient medium (col. 3, lines 64-66). Components of the nutrient

medium trigger the enzymatic reduction of the bacteria, just as required by the claims (col. 4, lines 3-15). The necessary metabolites can be present in the nutrient medium prior to exposing the composition to a blood sample (col. 4, lines 16-20). The test can also be performed in substances other than blood (col. 5, lines 11-13). Thus the art teaches the instantly claimed sample type. Thus the development of the blue color is indicative of the presence of microorganisms (col. 5, lines 3-6). Therefore Shih et al., teach a simple and effective test which can be carried out quickly and efficiently and it is understood that changes may be made in the details of the operations without departing from the spirit of the invention (col. 5, lines 25-32). However Shih et al., do not teach the conjugation of primary antibodies with reporter molecules and their detection.

Litman et al., methods for performing protein binding assays involving homologous pairs consisting of a ligand and receptor (see abstract). Litman et al., teaches that a main consideration for using immunoassays is their sensitivity (col. 2, lines 36-38). Litman et al., teaches that a receptor can be an antibody and one member of the pair is bound to a label capable of providing a detectable signal (col. 1, lines 15-19). Generally, useful heterogeneous labels include radiolabels, enzymes and fluorescent molecules (col. 2, lines 34-36). Litman et al., use physiological fluid samples and particles in the assays (col. 3, lines 33-37). Ligands can be any organic compound for which a receptor exists (col. 5, lines 30-32) while a receptor or anti-ligand can be any compound or composition capable of recognizing the ligand molecule or epitopic site. Thereby teaching the binding of the, for instance the viability marker. Receptors can bind proteins, enzymes and the like (col. 20-24). Thus enzymes, (like the

viability marker) may be part of a signal producing system may be involved as conjugates where they interact with a product or a signal label (col. 24, lines 35-45). Signal producing systems can have components being conjugated to a specific binding pair and then be detected (col. 6 lines 5-30). Litman et al., also defines labels, binding pair label, and labeled receptors (col. 6 lines 25-65). Table 1 illustrates different binding pair complexes and means by which a signal producing systems and reagents can be combined. For instance, the antibody specifically binds the enzyme (viability marker) and then be conjugated to a particle (see Table 1). Thereby teach the reporter-antibody complexes, just as required by the claims.

Therefore, it would have been prima facie obvious at the time of applicants' invention to modify the detection of the viability marker as taught by Shih et al., to instead include detection using an antibody. Moreover, one of ordinary skill in the art would have had a reasonable expectation of success, since the modified method taught by Shih et al., would generate more sensitive immunoassays. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success because one of ordinary skill in the art would have been motivated to make such changes in method since it is well known in the art of immunoassays to use antibodies specific and sensitive within the colorimetric assays taught by Shih et al.

Conclusion

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
December 26, 2006